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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,795	07/22/2003	Alastair McIndoe Hodges	104978-0007	7470
21125	7590	06/28/2005	EXAMINER	
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			NOGUEROLA, ALEXANDER STEPHAN	
			ART UNIT	PAPER NUMBER
			1753	

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/624,795	HODGES ET AL.	
	Examiner	Art Unit	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 22 July 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. 08/981,385.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>01/22/2003</u> .	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> .
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Continuation of Attachment(s) 6. Other: IDS of 3/18/2005 and IDS of 9/20/2004.

**DETAILED ACTION**

***Information Disclosure Statement***

1. Applicants are requested to provide copies of the following documents that are cited on the Information Disclosure Statement of January 22, 2003 ("IDS"), but were not found in the parent applications

SU 1351-627 A,

AU A 54873/94,

AU A 31042/93,

JP 466112 A,

JP 3167464,

JP 6222874,

DE 3103-464,

DE 3103464 A1, and

all of the documents cited in "Other Documents", which is on sheets 4-5 of the IDS.

***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Double Patenting Rejections Based on copending U.S. Application No. 10/624,823**

3. Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of copending Application No. 10/624,823 in view of Diebold et al. (US 5,437,999) ("Diebold") and Broderick (US 5,443,710) ("Broderick"). Claim 6 of copending Application No. 10/624,823 meets all of the limitations of claim 1 of the instant application except for the requirement of a fluid permeable side-wall on at least one side of the hollow cell permitting entry of the sample into the hollow cell, means for applying an electrical potential, and means for measuring a current as claimed. Diebold discloses an electrochemical sensor having a spacer made of non-conductive polymer interposed between a working electrode and a counter electrode. See Figure 5 and

col. 7:55-57. The spacer forms a hollow cell and a fluid permeable side-wall on at least one side of the hollow cell permitting entry of the sample into the hollow cell. See Figures 5 and 6. It would have been obvious to use a spacer made of non-conductive polymer in the invention of claim 1 of the instant application because such a spacer will allow the working electrode and the counter electrode to be positioned in a non-coplanar arrangement, yet be closely spaced and have a small, well-defined effective cell volume, and because the cell volume is in the shape of a capillary it spontaneously draws in sample through the fluid permeable side-wall and prevents contamination of the meter. See col. 8:45-60. The spacer is non-conductive to avoid short-circuiting of the working and counter electrodes. As for means for applying an electrical potential, and means for measuring a current, amperometry was one of several well –known electrochemical measurement techniques at the time of the invention (See col. 15:65 – col. 16:3 in Broderck. Diebold performs amperometry, e.g..), so barring a showing to the contrary, such as unexpected results, the choice of electrical means for performing the measurement will depend on the sample/analyte and what is to be determined, such as identification, such as trace detection (for which cyclic voltammetry was commonly used), or concentration (for which amperometry was commonly used).

This is a provisional obviousness-type double patenting rejection.

4. Claim 2 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of copending Application No. 10/624,823 in view of Diebold et al. (US 5,437,999) ("Diebold") and Broderick (US 5,443,710) ("Broderick"). Claim 1, from which claim 2 depends, has been addressed. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 2 of copending Application No. 10/624,823 provides the same additional limitation as claim 2 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claim 3 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/624,823 in view of Diebold et al. (US 5,437,999) ("Diebold") and Broderick (US 5,443,710) ("Broderick"). Claim 2, from which claim 3 depends, has been addressed. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 3 of copending Application No. 10/624,823 provides the same additional limitation as claim 3 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claim 4 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 4 of copending Application No. 10/624,823 in view of Diebold et al. (US 5,437,999) ("Diebold") and Broderick (US 5,443,710) ("Broderick"). Claim 3, from which claim 4 depends, has been addressed. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 4 of copending Application No. 10/624,823 provides the same additional limitation as claim 4 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claim 5 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 10/624,823 in view of Diebold et al. (US 5,437,999) ("Diebold") and Broderick (US 5,443,710) ("Broderick"). Claim 4, from which claim 5 depends, has been addressed. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 5 of copending Application No. 10/624,823 provides the same additional limitation as claim 5 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claim 6 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 10/624,823 in view of Diebold et al. (US 5,437,999) ("Diebold") and Broderick (US 5,443,710) ("Broderick"). Claim 5, from which claim 6 depends, has been addressed. Although the conflicting claims are not identical, they are not patentably distinct from each other because as stated in the region claim 1 above, "The spacer [of Diebold, which is to be used in the invention of claim 1 of copending Application No. 10/624,823] forms a hollow cell and a fluid permeable side-wall on at least one side of the hollow cell permitting entry of the sample into the hollow cell."

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Double Patenting Rejections Based on copending U.S. Application No. 10/624,746

9. Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/624,746. Although the conflicting claims are not identical, they are

not patentably distinct from each other because amperometry was one of several well-known electrochemical measurement techniques at the time of the invention (See col. 15:65 – col. 16:3 in Broderck), so barring a showing to the contrary, such as unexpected results, the choice of electrical means for performing the measurement will depend on the sample/analyte and what is to be determined, such as identification, such as trace detection (for which cyclic voltammetry was commonly used), or concentration (for which amperometry, and thus means for applying an electrical potential and means for measuring a current as claimed, was commonly used).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claim 2 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of copending Application No. 10/624,746 in view of Diebold et al. (US 5,437,999) ("Diebold") and Broderick (US 5,443,710) ("Broderick"). Claim 1, from which claim 2 depends, has been addressed. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 2 of copending Application No. 10/624,746 provides the same additional limitation as claim 2 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claim 3 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/624,746 in view of Diebold et al. (US 5,437,999) ("Diebold") and Broderick (US 5,443,710) ("Broderick"). Claim 2, from which claim 3 depends, has been addressed. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 3 of copending Application No. 10/624,746 provides the same additional limitation as claim 3 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claim 4 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 4 of copending Application No. 10/624,746 in view of Diebold et al. (US 5,437,999) ("Diebold") and Broderick (US 5,443,710) ("Broderick"). Claim 3, from which claim 4 depends, has been addressed. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 4 of copending Application No. 10/624,746 provides the same additional limitation as claim 4 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claim 5 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 10/624,746 in view of Diebold et al. (US 5,437,999) ("Diebold") and Broderick (US 5,443,710) ("Broderick"). Claim 4, from which claim 5 depends, has been addressed. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 5 of copending Application No. 10/624,746 provides the same additional limitation as claim 5 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claim 6 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 10/624,746 in view of Diebold et al. (US 5,437,999) ("Diebold") and Broderick (US 5,443,710) ("Broderick"). Claim 5, from which claim 6 depends, has been addressed. Although the conflicting claims are not identical, they are not patentably distinct from each other because as stated in the region claim 1 above, "The spacer [of Diebold, which is to be used in the invention of claim 1 of copending Application No. 10/624,746] forms a hollow cell and a fluid permeable side-wall on at least one side of the hollow cell permitting entry of the sample into the hollow cell."

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Double Patenting Rejections Based on U.S. 6,284,125 B1

15. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 24, 31, 57, and 58 of U.S. Patent No. 6,284,125 B1 in view of Diebold et al. (US 5,437,999) ("Diebold") and Broderick (US 5,443,710) ("Broderick"). The combination claims 24, 25, 31, and 58 of U.S. Patent No. 6,284,125 B1 meets all of the limitations of claim 1 of the instant application except for the requirement of a spacer made of non-conductive polymer interposed between the working electrode and the counter electrode, a fluid permeable side-wall on at least one side of the hollow cell permitting entry of the sample into the hollow cell, means for applying an electrical potential, and means for measuring a current as claimed.

Diebold discloses an electrochemical sensor having a spacer made of non-conductive polymer interposed between a working electrode and a counter electrode. See Figure 5 and col. 7:55-57. The spacer forms a hollow cell and a fluid permeable side-wall on at least one side of the hollow cell permitting entry of the sample into the hollow cell. See Figures 5 and 6. It would have been obvious to use a spacer made of

non-conductive polymer in the invention of claim 1 of the instant application because such a spacer will allow the working electrode and the counter electrode to be positioned in a non-coplanar arrangement, yet be closely spaced and have a small, well-defined effective cell volume, and because the cell volume is in the shape of a capillary it spontaneously draws in sample through the fluid permeable side-wall and prevents contamination of the meter. See col. 8:45-60. The spacer is non-conductive to avoid short-circuiting of the working and counter electrodes. As for means for applying an electrical potential, and means for measuring a current, amperometry was one of several well –known electrochemical measurement techniques at the time of the invention (See col. 15:65 – col. 16:3 in Broderck. Diebold performs amperometry, e.g..), so barring a showing to the contrary, such as unexpected results, the choice of electrical means for performing the measurement will depend on the sample/analyte and what is to be determined, such as identification, such as trace detection (for which cyclic voltammetry was commonly used), or concentration (for which amperometry was commonly used).

16. Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 24, 32, 57, and 58 of U.S. Patent No. 6,284,125 B1 in view of Diebold et al. (US 5,437,999) ("Diebold") and Broderick (US 5,443,710) ("Broderick"). Claim 1, from which claim 2 depends, has been addressed above.

Claim 32 of U.S. Patent No. 6,284,125 B1 meets the additional limitation of claim 2 of the instant application.

17. Claim 3 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 24, 32, 34, 57, and 58 of U.S. Patent No. 6,284,125 B1 in view of Diebold et al. (US 5,437,999) ("Diebold") and Broderick (US 5,443,710) ("Broderick"). Claim 2, from which claim 3 depends, has been addressed above.

Claim 34 of U.S. Patent No. 6,284,125 B1 meets the additional limitation of claim 3 of the instant application.

18. Claim 4 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 24, 32, 34, 57, and 58 of U.S. Patent No. 6,284,125 B1 in view of Diebold et al. (US 5,437,999) ("Diebold"). Claim 3, from which claim 4 depends, has been addressed above.

Claim 34 of U.S. Patent No. 6,284,125 B1 meets the additional limitation of claim 4 of the instant application.

19. Claim 5 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 24, 29, 32, 34, 38, 57, and 58 of U.S. Patent No. 6,284,125 B1 in view of Diebold et al. (US 5,437,999) ("Diebold"). Claim 4, from which claim 5 depends, has been addressed above.

Claims 29 and 38 of U.S. Patent No. 6,284,125 B1 meet the additional limitation of claim 5 of the instant application.

20. Claim 6 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24, 29, 32, 34, 38, 57, and 58 of U.S. Patent No. 6,284,125 B1 in view of Diebold et al. (US 5,437,999) ("Diebold") and Broderick (US 5,443,710) ("Broderick"). Claim 5, from which claim 6 depends, has been addressed. Although the conflicting claims are not identical, they are not patentably distinct from each other because as stated in the rejection claim 1 above, "The spacer [of Diebold, which is to be used in the invention of claim 1 of copending Application No. 10/624,746] forms a hollow cell and a fluid permeable side-wall on at least one side of the hollow cell permitting entry of the sample into the hollow cell."

***Claim Rejections - 35 USC § 103***

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

23. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

24. Claims 1-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold et al. (US 5,437,999) in view of Straus et al. (US 5,089,320) ("Straus").

Addressing claim 1, Diebold discloses an apparatus for determining a concentration of glucose in a blood sample, the apparatus comprising

(a) a hollow electrochemical cell (Figures 5 and 6), the cell comprising

(1) at least one working electrode (11);

(2) at least one counter or counter/reference electrode (48), wherein the working electrode and the counter or counter/ reference electrode are not coplanar (Figure 5) and a separated by a very small distance (implied by Figure 5 and related passages, which disclose thin layers);

(3) a spacer (43) interposed between the working electrode and the counter electrode or counter/reference electrode (Figure 5), where the spacer comprises a non-conductive polymeric material (col. 7:14-18 and col. 7:55-57), and wherein the hollow electrochemical cell has a small effective volume (implied and by col. 8:45-50, which discloses that the cell is part of a capillary space); and

(4) a fluid permeable side-wall on at least one side of the hollow cell permitting entry of the sample into the hollow cell (right end of capillary 49 in Figure 5);

(b) means for applying an electrical potential difference between the working and the counter electrode or counter/reference electrode (implied by col. 12:68 – col. 13:2, which discloses applying a potential difference across the working electrode and the reference electrode); and

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(c) means for measuring a current between the working electrode and the counter electrode or counter/reference electrode (implied by col. 13:4-16, which discloses measuring current and a meter for measuring current).

Diebold does not mention (1) whether the working electrode in the embodiment of Figure 5 is non-metal, (2) having the working electrode and the counter or counter/reference electrode spaced from about 20 microns to about 200 microns, and (3) having the effective cell volume be less than 1.5 microliters

As for having the working electrode be non-metal, Diebold does broadly disclose providing a non-metal working electrode. Diebold states, "A working, counter, or reference electrode element may be produced in accordance with the present invention as shown in Fig. 1. Electrically conducting material 1 (e.g., a noble metal or carbon) is vacuum sputtered or evaporatively deposited onto thin support material 2 ..." [emphasis added]. See col. 3:50-54. The decision as to whether to use a metal working electrode or a non-metal working electrode was within the skill of one with ordinary skill in the art at the time of the invention. The major factors that would be considered are manufacturing cost for and retail price of the electrochemical cell (noble metals, such as gold and platinum are more expensive than carbon) and desired measurement accuracy (electrical conductivity of the conductive material for the electrode).

As for the working electrode and the counter or counter/reference electrode spaced from about 20 microns to about 200 microns, Diebold discloses using a MYLAR™ film as a spacer (col. 7:14-18 and col. 7:55-57), but does not disclose the thickness. Diebold also discloses using MYLAR™ film of approximately 10 mil (254

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microns) thickness as an electrode support (col. 5: 62-67), which if not the same MYLAR™ film as used for the spacer is certainly an obvious variant. As shown by Straus, at the time of the invention MYLAR™ film of only 12.2 microns in thickness was commercially available. See col. 4:53-56. Barring evidence to the contrary, such as unexpected results Applicants' claimed distance between the working electrode and the counter or counter/reference electrode of from about 20 microns to about 200 microns is just a matter of scaling the spacer of Diebold, such as by using the 12.2 micron thick Dupont Mylar film disclosed by Straus. A smaller spacer will create a smaller electrochemical cell effective volume, which is consistent with the purpose of Diebold: "A method for fabricating high-resolution, biocompatible electrodes is disclosed, allowing production of an electrochemical sensor which is capable of precise analyte concentration determination on a very small sample size. [emphasis added]"

As for the hollow electrochemical cell having an effective cell volume of less than 1.5 microliters, this is just a matter of scaling the spacer of Diebold. Diebold is directed to a small volume sensor and discloses a cell volume of 3 microns. See the abstract, and col. 12:35-42. The spacer, by its thickness and the width of the capillary channel, defines the cell volume in Diebold. See Figure 5. It may be made of a plastic film, such as MYLAR™ film. See Figure 5 and col. 7:14-18 and col. 7:55-57. As noted above, at the time of the invention MYLAR™ film of only 12.2 microns in thickness was commercially available. Diebold also discloses using a laser to from a cutout that defines the capillary channel. See col. 7:14-21. Thus, barring evidence to the contrary, such as unexpected results, having an effective cell volume of less than 1.5 microliters

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is just a matter of scaling the cell volume in Diebold by using a thin enough spacer, such as using the 12.2 micron thick Dupont Mylar film disclosed by Straus, and/or creating a narrow enough capillary channel by using thin enough laser beam.

Addressing claim 2, as discussed in the rejection of claim 1 Diebold discloses a carbon working electrode.

Addressing claims 3 and 4, Diebold states, "A working, counter, or reface electrode element may be produced in accordance with the present invention as shown in Fig. 1. Electrically conducting material 1 (e.g., a noble metal or carbon) is vacuum sputtered or evaporatively deposited onto thin support material 2 ..." [emphasis added]. See col. 3:50-54. So, barring evidence to the contrary, such as unexpected results, whether to use a noble metal for the counter electrode and a nonmetal for the working electrode is just a matter of optimizing the electrochemical cell (sensor), while minimizing cost.

Addressing claim 6, as stated in the rejection claim 1 above, "The spacer [of Diebold, which is to be used in the invention of claim 1 of copending Application No. 10/624,746] forms a hollow cell and a fluid permeable side-wall on at least one side of the hollow cell permitting entry of the sample into the hollow cell."

25. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold et al. (US 5,437,999) in view of Straus et al. (US 5,089,320) ("Straus") as applied to claims 1-4 and 6 above, and further in view of Carter et al. (US 5,126,034) ("Carter") and Bohs (US 5,399,256).

As for the metal being silver, since Diebold discloses that the metal may be a noble metal this is just optimization. In fact, Diebold discloses a counter electrode comprising silver (col. 12:43-55). Ag/AgCl was a common counter/reference electrode composition at the time of the invention. As shown by Carter and Bohs the combination of a non-metal (carbon) working electrode and a silver counter/ reference electrode is not novel. See Figure 1 and col. 2:28-48 in Carter and Figure 5; col. 2:62- col. 3:5;and col. 7:50-53 in Bohs.

As for chloride ions in the blood sample, the type of sample is intended use that does not appear to further structurally limit the electrochemical cell. In a any event, Diebold discloses directly measuring blood (col. 12: 35-42) and blood contains various chloride salts, such as NaCl or KCl.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguerola  
Primary Examiner  
AU 1753  
June 24, 2005